Original Article

The accuracy of Breastlight in detection of breast lesions

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Abstract

AIM: Breastlight is a new product to improve breast health awareness of women. However, its accuracy in detection of breast lesions (BLs) is unknown. The aim of this study was to determine the Breastlight accuracy in detection of BLs. **MATERIALS AND METHODS:** From July 2011 to September 2013, a total of 500 women referred to mammography unit in Yazd, Iran for screening were recruited to the study. The sensitivity and specificity of Breast light was measured with clinical breast examination (CBE), mammography and sonography. Sonographic and mammography examinations were performed according to breast density among women in two groups of younger (n = 105) and older (n = 395) than 30 years. **RESULTS:** The results have shown a statistically significant positive correlation between Breastlight, CBE, sonography, and mammography in detection of BLs. Breastlight significantly detected 60.3%, 35.8%, and 59% of lesions which were detected by mammography, CBE, and sonography, respectively. Its sensitivity varied significantly with breast density. Comparing the sensitivity of Breastlight among women younger and older than 30 years indicated that the Breastlight had a higher sensitivity for women older than 30 years. The greatest and lowest portion of positive predictive value occurred with CBE (94.7%) and mammography (91.1%). As well, its greatest and lowest portion of negative predictive value occurred with CBE (65.6%) and sonography (29.7%). **CONCLUSION:** The results of this study showed that the efficacy of Breastlight in detection of breast changes as domestic apparatus was appropriate. However, it is recommended further studies to evaluate the Breastlight efficacy and accuracy in detection of the BLs.

Key Words: Breast cancer, Breastlight, clinical breast examination, mammography, sonography

Introduction

Breast cancer is the most frequently diagnosed cancer worldwide, and the leading cause of cancer death among females.[1] Improved breast cancer awareness, screening and improved treatment probably contributed to the decrease in breast cancer mortality. Identifying breast cancer at early stage is most effectively performed by screening modalities.[2] Mammography is the primary imaging modality for breast cancer screening in early stages. It has been proven that early detection of breast cancer through mammography, decrease breast cancer mortality.[3] Its sensitivity reported between 83% and 95%. Although the cost of mammography is relatively low, its moderate sensitivity for breast cancer detection does not make mammography a perfect screening test. Its sensitivity is affected by different factors such as age, breast density, tumor or lesions depth and body mass index that lead to false negative results.[4]

Combinations of mammography with other modalities, including palpation, ultrasonography, magnetic resonance imaging or breast tomosynthesis, have been investigated with the purpose to increase the sensitivity of breast cancer screening. Clinical breast examination (CBE) by palpation, in addition to mammography, results in a 4% increase of the sensitivity.[5]

It seems that CBE is effective in the diagnosis of suspicious lesions by increasing women's awareness toward breasts changes. The CBE sensitivity and specificity have been reported vary from 28% to 36%.[6] Therefore, CBE is recommended to be used along with mammography or other tests.[7]

Breastlight is a new product which is designed for use at home to improve breast health awareness. Breastlight shines a harmless red light (617 nm) through the breast tissue which absorbed by hemoglobin, so that denser spots such as malignant tumors should appear black. According to a few studies, it has been recommended that using Breastlight at home with breast self-examination (BSE) and or by CBE can increase the positive screening results and women's awareness.[8,9]

The main objective of the present study was to evaluate the diagnostic accuracy of the Breastlight with CBE, mammography and sonography in the detection of breast lesions (BLs).

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Materials and Methods

The study participants consisted of 500 women referred by general practitioners or specialists to the Radiology Department of a Teaching Hospital in Yazd, Iran for screening mammography between July 2011 and September 2013 were included in the study. Most women are older than 30 years who were referred because of mastalgia or an increased risk of developing breast cancer. The mean (standard error) age at enrollment was 37 ± 4.2 years, with a range of 19–49 years.

A written informed consent obtained from all the participants. Furthermore, this study was approved by the Ethics Committee of Medical Faculty, Shahid Sadoughi University of Medical Sciences and Health Services, Yazd, Iran.

Study design

After the CBE, mammography, and sonography, the next diagnostic step was Breastlight. CBE, mammography, sonography and Breastlight assessments were performed by three different experienced physicians blinded to the results of other modalities. In this series, of 500 women, mammography examinations were performed in 395 women older than 30 years and sonography was performed in 105 women younger than 30 years due to the breast density.

Clinical breast examination

Physical examination of the breasts and regional lymphatic areas was performed by a physician experienced in breast examination. With the patient in the supine position and

one arm raised, the physician thoroughly palpates breast tissue on the raised-arm side in the superficial, intermediate, and deep tissue planes; axilla, supraclavicular area, neck, and chest wall at least for 5 min. In premenopausal women, the CBE is best performed the week following menses, when breast tissue is least engorged.

Mammography

Conventional film-screen mammography was performed with at least two views per breast (mediolateral oblique and craniocaudal views). Additional views or spot compression views were obtained where appropriate. Mammograms were obtained with dedicated mammography units (Alpha RT Imaging, General Electric Medical Systems, Milwaukee, Wisconsin, US). Patients younger than 30 years were excluded, because mammography is not performed in this age group.

Sonography

High-resolution ultrasound was performed by an experienced physician. All breast sonographic evaluations were performed with the patient in a supine position for the medial parts of the breast and a contralateral posterior oblique position with arms raised for the lateral parts of the breast. The sonograms were obtained using real-time technique with 7.5–13 MHz transducers (Siemens Elegra, GE Logic 500, and ATL HDI 5000; Siemens, Erlangen, Germany). Targeted sonographic examinations were performed first by the radiologic technologist and rescanned by the interpreting physician for all the women.

Statistical analysis

All the statistical analyzes in this study were performed using SPSS for Windows software (SPSS Inc, Chicago, IL, USA). Chi-square test and Student's *t*-test were used for statistical data processing. Kappa (κ) measure was used to assess the agreement between breast illumination method and mammogram. The significance of differences was assessed using Pearson's Chi-square test, with $P < 0.05$ considered to be statistically significant.

The diagnostic yield (i.e. the proportion of women with a positive screen test and positive reference standard), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were estimated by standard formula and its coefficient of agreement with respect to the gold standards.

Results

Table 1 shows that, of all lesions, 3.3% were correctly identified on Breastlight, but missed with mammography, and 22.2% were correctly identified mammography, but were not detected by Breastlight. Breastlight was false negative in 266 (62.9%) out of 423 cases; while mammography was false negative in 186 out of 423 cases.

Comparing the sensitivity of Breastlight and mammography, indicated that Breastlight could significantly detect 60.3% of lesions, which was detected by mammography ($P = 0.0001$). The κ value for the agreement between the Breastlight and mammography was 0.51. Therefore, these results demonstrated a statistically significant positive correlation between Breastlight and mammography.

Table 1: Correlation between Breastlight and mammography for BLs

	Mammography (%)		Total (%)
	Positive	Negative	
BL			
Positive	134 (33.8)	13 (3.3)	147 (37.2)
Negative	88 (22.2)	160 (40.6)	248 (62.8)
Total	222 (56.2)	173 (43.8)	395 (100)

BLs=Breast lesions

Table 2 shows that, of all lesions, 1.9% were correctly identified as lesion on Breastlight, but were not correctly identified with sonography, and 49.5% were correctly identified by sonography, but not with Breastlight. The results of Breastlight were false negative in 74 (70.5%) of 105 women with dense breast; while false negative results of sonography were 24 out of 105 lesions.

Comparing the sensitivity of Breastlight and sonography, indicated that Breastlight significantly detected 35.8% of lesions, which was detected by sonography ($P = 0.01$). The κ value for the agreement between the Breastlight and sonography was 0.016. Therefore, these results demonstrated a statistically significant positive correlation between Breastlight and sonography.

Table 3 shows that, of all lesions, 0.18% were correctly identified on Breastlight, but not correctly identified on CBE, and 22.6% were correctly identified on CBE, but not Breastlight. Breastlight was false negative in 328 (65.6%) out of 500 lesions; CBE was false negative in 224 out of 500 lesions.

Comparing the sensitivity of Breastlight and CBE, indicates that Breastlight significantly detected 59% of lesions, which was detected by CBE ($P = 0.0001$). The κ value for the agreement between the Breastlight and CBE was 0.53%. Therefore, these results demonstrated a statistically significant positive correlation between Breastlight and CBE.

Discussion

In 1929, optical scanning was introduced as a noninvasive instrument for breast examination by Cutler.[10,11] Since, several new techniques including BL have been invented based on optics for detecting BLs. This instrument operates on the basis of absorption at 550 nm. Based on the previous studies, its sensitivity was estimated 67–73%.[11]

The present research is one of the few studies which tried out to evaluate the sensitivity, specificity, PPV, NPV, efficiency (overall agreement), κ and correlation coefficient of the BL, and comparing it with the three other most commonly used reference tests for the diagnosis of BLs.

The ideal test is one that has very high sensitivity and specificity, so that most true cases are identified, and most noncases are excluded.[12] In the present study, the highest sensitivity and specificity of BL were obtained toward mammography and CBE, respectively [Table 4].

Table 2: Correlation between Breastlight and sonography for BLs

	Sonography (%)		Total (%)
	Positive	Negative	
BL			
Positive	29 (27.6)	2 (1.9)	31 (29.5)
Negative	52 (49.5)	22 (20.9)	74 (70.5)
Total	81 (77.1)	24 (22.9)	105 (100)

BLs=Breast lesions

Table 3: Correlation between breastlight and CBE for BLs

	CBE (%)		Total (%)
	Positive	Negative	
BL			
Positive	163 (32.6)	9 (0.18)	172 (34.4)
Negative	113 (22.6)	215 (43)	328 (65.6)
Total	276 (55.2)	224 (44.8)	500

BLs=Breast lesions; CBE=Clinical breast examination

Table 4: Breastlight sensitivity, specificity, PPV and NPV with mammography, sonography and CBE

	Sensitivity %	Specificity %	PPV %	NPV %	κ %	*P*
BL and CBE	59	96	94.7	65.6	53	0.001
BL and mammography	60.3	92.5	91.1	64.7	51	0.001
BL and sonography	35.8	91.7	93.5	29.7	16	0.01

BL=Breast lesion; CBE=Clinical breast examination; PPV=Positive predictive value; NPV=Negative predictive value

As well, the results have shown that the sensitivity and specificity of the BL was very low when compared with the sonography [Table 2]. The main factors influencing the low sensitivity (83%) could be due to the breast density.

As shown in Table 1, of all cases, 3.3% were correctly identified as lesion on BL but not correctly identified with mammography, and 22.2% were correctly identified on mammography but not on BL. Combining the two tests, if either test is positive, gives a high sensitivity of approximately 33.8%. Nonetheless, about 40.6% of lesions will be misdiagnosed when combining mammography and BL. The PPV and NPV in this study were 91.1% and 64.7%. PPV of BL is the proportion of patients with positive mammography test who are correctly diagnosed. It reflects the probability that a positive test reflects the underlying condition being tested for. NPV is the proportion of patients with negative lesions who are correctly diagnosed. Therefore, if a patient has a positive lesion, there is 64.7% chance of having a lesion or a quarter does not have a lesion. For women under 30 years old, the sensitivity and specificity of the BL comparing to sonography was 35.8% (κ =16%, P = 0.01) and 91.7%, respectively. The PPVs and NPVs were 93.5% and 29.7%, respectively. In this study the sensitivity and specificity of BL with CBE was calculated 59% and 96%, respectively (PPV = 94.7%, NPV = 65.5%; κ =53%). Results showed shown that the sensitivity and specificity of BL with CBE was higher than sonography and resembles those of mammography (P < 0.001). Furthermore, its PPV and NPV in comparison with CBE were estimated higher than the two other tests. This result seems to be logical because CBE is a technique that depends on the physician's skill.

However, specificity of BL in comparison with CBE was more than other techniques. This means that the BL could resolve CBE errors. Sensitivity and specificity of CBE if performed well, for detecting asymptotic BLs has been reported 57% and 97%, respectively. A study reported its sensitivity up to 21% alone, while the sensitivity of BL has been reported only 67%.[11] Just like BSE; there is a doubt about the reduction of mortality by CBE. However, CBE is useful for the detection of suspicious cases.[13,14]

According to the reports, mammography is a technique which decreases the rate of mortality of breast cancer, but because of the higher density of breast in younger women (lower than 40 years), the sensitivity of this technique does not have meaningful results. Therefore, sonography alone or along with mammography is recommended for younger women. Due to the influence of various factors such as age and menstrual periods, the detection capability of BL has reported 67% to 73%, while it is reported 60% to 90% for mammography.[14,15] For women older than 50 years, the sensitivity of mammography is heterogeneous. Its reported that the sensitivity of mammography among women older and younger than 50 years is 52.4% and 90.5%, respectively.[16] In a study that is conducted to evaluate the sensitivity of BL among 56 women; in two groups of women older and younger than 50 years, its sensitivity has been reported 97% and 92%, respectively.[11] In another study, the sensitivity and specificity of mammography for women between 40 and 44 years have been reported 68.6%, and for women of between 80 and 89 years, it has been reported 83.3%.[13] The sensitivity of mammography for breasts with high density is 62.9%, whereas it is 87% for fatty breasts. We found that the sensitivity and specificity of BL in comparison with mammography for women over 30 are 60.3% and 92.5%, respectively.

Compared with mammography, the sensitivity of BL obtained by this study was greater than other techniques. Its PPV was less than other tests, which confirm the reduction of sensitivity of mammography among young women. Therefore, BL can be used along with mammography for younger cases. In a multicenter Swedish study, light scanning versus mammography was tested among 2568 women. The obtained outcomes showed that the mammography alone falsely diagnosed cancer in 6.9% of the participants, whereas false diagnosis of cancer with light scan was 19.1%.[17]

Recently a study was conducted in Cairo to evaluate the properties of Breastlight in early detection of BLs in comparison with mammography. The study reported sensitivity, specificity, PPV, NPV and total accuracy of Breastlight method 93.0%, 73.7%, 91.4%, 77.8%, and 88.2%, respectively. Their reported sensitivity proportion was

greater than the results of the present study.[18] However, the specificity proportion status was vice versa [Table 4]. The results of BL are not affected by breast density and age. In addition, BL can be used to confirm the results of mammography. BL can be useful for women in all age groups based on obtaining results of sensitivity and coefficient of agreement, but cannot be an alternative to mammography. Furthermore, for young women with dense breasts, sonography is recommended along with mammography. The size of BL has detective and therapeutic value. Studies have shown that while mammography is not suitable for detecting lesions upon the size, but BL can detect up to 29% of palpable lesions (<7 mm).[11] The results of our study show that BL detection capability compared to mammography was enhanced by the growth of BL ($P < 0.00$). A review study showed that one in every two women has false positive mammography results, which increased their stress and anxiety, which in turn this consequence is considered as a risk factor for some cancers.[16] However, studies among women show that they feel more confident by BL (82%).

Sonography with mammography and BSE are a useful technique for the early detection of breast cancer. In a study which was conducted among 156 women based on the disease stage, breast density and lesions palpation, it was shown that the sensitivity of mammography is affected by the factors while the sensitivity of sonography is not affected by such factors. Our results also showed that the sensitivity and specificity of BL toward sonography among women younger than 30 years old were 35.8% and 91.7%, respectively. One of the reported weaknesses for sonography is the reduction of its sensitivity for impalpable lesions, especially for micro-calcifications, while BL has the sensitivity of 28% for the tumors smaller than 7 mm and impalpable ones.[19] Moreover, benign cysts cannot be examined positively by BL.

Conclusion

In this study, obtained sensitivity and NPV of BL with sonography was less than other modalities. Therefore, results confirm the higher efficiency of sonography for younger women with dense breasts. The results of this study clearly show the benefits of BL, which based on criteria of other techniques, possesses the capability of detecting lost and faulty detected cases. Since BL in this study has been performed by a skilled physician; for studying the results of screening in the form of "self-examination;" it is recommended that this issue is performed by the women themselves, and its decreasing effects on the mortality of breast cancers be examined. This study had a limitation, in which we did not survey the BL positive and negative results in conformity with pathological results. This is one of the few attempts to identify the BL sensitivity and specificity towards CBE, sonography and mammography. We recommended more studies to evaluate the BL advantage and disadvantages in BL detection. We supposed that BL can be used as a home use tools for increasing women's awareness about their breast changes, or for BSE.

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